

Exhibit B

Jimmy W. Mays, Ph.D.

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 -----§
5 IN RE: BOSTON SCIENTIFIC CORP., § MDL NO. 2326
6 PELVIC REPAIR SYSTEM PRODUCTS §
7 LIABILITY LITIGATION §

8 -----§

9 THIS DOCUMENT RELATES TO: §
10 §
11 ALL WAVE 4 CASES IN MDL NO. 2326 §
12 §

13 -----§

14 - - -
15 Thursday, August 16, 2018
16 - - -

17 Videotaped deposition of JIMMY W. MAYS, Ph.D.,
18 held at the JW Marriott Marco Island Beach
19 Resort, 400 South Collier Boulevard, Marco
20 Island, Florida, commencing at 9:08 a.m., on the
21 above date, before Susan D. Wasilewski,
22 Registered Professional Reporter, Certified
23 Realtime Reporter, Certified Realtime Captioner,
24 Certified Manager of Reporting Services, Florida
25 Professional Reporter, Certified Court Reporter
 (New Jersey), and Realtime Systems Administrator

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Jimmy W. Mays, Ph.D.

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I N D E X
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Testimony of: JIMMY W. MAYS, Ph.D. PAGE
DIRECT EXAMINATION BY MS. STEELE..... 6

E X H I B I T S

(Attached to transcript)

JIMMY W. MAYS, Ph.D. DEPOSITION EXHIBITS	PAGE
Exhibit 1 Notice of Videotaped Deposition Duces Tecum of Dr. Jimmy Mays, Ph.D.	6
Exhibit 2 Expert Report of Jimmy W. Mays, PhD., and Samuel P. Gido, Ph.D.	14
Exhibit 3 2014 Expert Report of Jimmy W. Mays, Ph.D.	15
Exhibit 4 June 2018 Expert Report of Jimmy Mays, Ph.D.	16
Exhibit 5 Exhibits A, B and C of Expert Report of Jimmy W. Mays, Ph.D.	17
Exhibit 6 Article: In vivo oxidative degradation of polypropylene pelvic mesh By Adam Imel, et al.	29
Exhibit 7 Article: Oxidation and degradation of polypropylene transvaginal mesh By Anne D. Talley, et al.	32
Exhibit 8 Article: The myth: In vivo degradation of polypropylene-based meshes By Shelby F. Thames, et al.	48

Jimmy W. Mays, Ph.D.

1	E X H I B I T S		
2	(Attached to transcript)		
3	JIMMY W. MAYS, Ph.D. DEPOSITION EXHIBITS	PAGE	
4	Exhibit 9 Letter to the Editor: In vivo	48	
5	polypropylene mesh degradation is		
6	hardly a myth		
7	By Margaret Thompson, et al.		
8	Exhibit 10 Letter to the Editor: Reply to "In	48	
9	vivo polypropylene mesh degradation		
10	is hardly a myth"		
11	By Shelby F. Thames, et al.		
12	Exhibit 11 June 3, 2018 Expert Report and	7	
13	Curriculum Vitae		
14	Exhibit 12 June 7, 2018 Letter Invoice to Clark,	7	
15	Love & Hutson, GP		
16	Exhibit 13 Presentation: Use of High	13	
17	Temperature GPC to Characterize In		
18	Vivo Oxidative Degradation of		
19	Polypropylene		
20	By Jimmy Mays		
21	GPC2017, July 19, 2017		
22			
23			
24			
25			

Jimmy W. Mays, Ph.D.

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2

THE VIDEOGRAPHER: We are now on the record.

3

My name is Luana Pruitt. I am your videographer

4

for Golkow Litigation Services. This deposition

5

is being held in Marco Island, Florida, in the

6

matter of Boston Scientific Corp. Pelvic Repair

7

Systems Product Liability Litigation to be heard

8

before the United States District Court for the

9

Southern District of West Virginia.

10

Our deponent today is Jim Mays, Ph.D.

11

Will counsel please introduce themselves

12

beginning with plaintiff counsel.

13

MR. PERDUE: This is Jim Perdue, Jr., on

14

behalf of the Plaintiffs in the MDL.

15

MS. STEELE: And this is Andrea Steele on

16

behalf of the Defendant, Boston Scientific.

17

THE VIDEOGRAPHER: And will our court

18

reporter, Susan Wasilewski, please swear our

19

witness?

20

THE COURT REPORTER: Do you solemnly swear

21

or affirm the testimony you're about to give will

22

be the truth, the whole truth, and nothing but

23

the truth?

24

THE WITNESS: I do.

25

THE COURT REPORTER: Thank you.

Jimmy W. Mays, Ph.D.

1 JIMMY W. MAYS, Ph.D., called as a witness by
2 the Defendant, having been duly sworn, testified as
3 follows:

4 DIRECT EXAMINATION

5 BY MS. STEELE:

6 Q. Good morning, Dr. Mays.

7 A. Good morning.

8 (Mays Exhibit 1 was marked for
9 identification.)

10 BY MS. STEELE:

11 Q. I'm going to hand you what's been marked as
12 Exhibit 1, which is the notice to your deposition.
13 Have you seen this document before?

14 A. Yes, I have.

15 Q. And if you turn to page 3, pages 3 and 4 are
16 14 document requests in Exhibit A, and Counsel
17 handed me before the deposition a folder of
18 documents that you brought responsive to these
19 requests. Is that right?

20 A. Yes.

21 Q. And the first document is a copy of your
22 report that you served?

23 A. Correct.

24 Q. We'll mark -- and then you also brought a
25 copy of your curriculum vitae?

Jimmy W. Mays, Ph.D.

1 A. I did. That's the most up-to-date.

2 Q. Most up-to-date. And do you think there
3 were changes since you served your report in June?

4 A. They would have been extremely minor.

5 MS. STEELE: I'm going to go ahead and mark
6 the report, along with the updated CV, as
7 Exhibit 11 for the record.

8 (Mays Exhibit 11 was marked for
9 identification.)

10 (Mays Exhibit 12 was marked for
11 identification.)

12 BY MS. STEELE:

13 Q. And then Exhibit 12, I'm going to mark
14 the -- and this is an invoice from June 7th, 2018,
15 to Clark, Love & Hutson.

16 A. Correct.

17 Q. And this is for consulting work that you did
18 on what is basically an update to your general
19 report in this litigation. Is that accurate?

20 A. Yes, it is.

21 Q. And it looks like you -- for
22 specifically for -- we call this Wave 4. Do
23 you under -- so if I use the term "Wave 4," do you
24 understand?

25 A. Generally, yes. I don't know the specific

Jimmy W. Mays, Ph.D.

1 details but I understand that it has come in waves.

2 Q. Yes. So, generally, you understand that
3 you've served two other general expert reports in
4 the MDL before?

5 A. Yes, I did.

6 Q. And you served a third expert report that
7 updates certain sections in June of 2018, right?

8 A. Yes.

9 Q. And this invoice pertains in particular to
10 the updates that you made to the report that you
11 served in June?

12 A. Yes. Correct.

13 Q. And it looks like between May 14th, 2018, to
14 June 7, 2018, you spent 14 hours preparing your
15 updated report; is that right?

16 A. Yes.

17 Q. And so that your total invoice for updating
18 your report in the Boston Scientific MDL comes to
19 \$4,900; is that right?

20 A. That sounds right, yes.

21 Q. And have you performed any work related to
22 the Boston Scientific litigation since June 7th of
23 2018?

24 A. Only some preparation for this deposition
25 today.

Jimmy W. Mays, Ph.D.

1 Q. And approximately how much time have you
2 spent preparing for your deposition today?

3 A. Oh, this is a guess. I probably spent about
4 maybe 10 or 12 hours reviewing my prior depositions,
5 reviewing my report, looking at some documents that
6 I thought were relevant, and then I spent a couple
7 of hours with Mr. Perdue yesterday in preparation as
8 well, so maybe a total, I'm guessing, maybe 14
9 hours.

10 Q. And when you were reviewing your prior
11 deposition testimony, was there any testimony that
12 you reviewed that was inaccurate or your opinion has
13 changed since you gave that testimony?

14 A. You know, I saw a couple of little things
15 but they are very minor. I think I referred to
16 Dr. Thames' extensive way of treating the explants
17 to remove tissue as a 16-step procedure in the depo
18 we had prior, but it's really a 23-step procedure.
19 I don't know how I got 16 in my head, but -- I
20 noticed that but, otherwise, I noticed a typo or two
21 but nothing of any substance.

22 Q. Okay. And when you reviewed your prior
23 reports, and I have them with, so I can mark them
24 for you, too, were there any opinions stated in your
25 two prior expert reports in the Boston Scientific

Jimmy W. Mays, Ph.D.

1 MDL that have changed?

2 A. No.

3 Q. And in May of 2018, when you started working
4 on your updated report, how did that come to be that
5 you decided to update it?

6 A. I was contacted by Ms. Hutson, Shelley
7 Hutson, and she asked if I would prepare an update
8 for this new wave of cases.

9 Q. And can you describe the steps you took
10 after your conversation with Ms. Hutson to update
11 your report?

12 A. Yes. I went back and reviewed my prior
13 reports, I reviewed our paper published in
14 Biomaterials that contained our own testing data, I
15 did some literature searches to find new papers that
16 were out there where people investigated explanted
17 polypropylene, and that's really the start of
18 gathering the pertinent information and then making
19 the revisions.

20 Q. Did you conduct any further testing?

21 A. No.

22 Q. Since you were last deposed in a Boston
23 Scientific case, which you were deposed in December
24 2016 by myself and then you were deposed again in
25 another state court case in January 2017?

Jimmy W. Mays, Ph.D.

1 A. That sounds right, yes.

2 Q. And since that time have you performed any
3 testing on polypropylene mesh?

4 A. Not on polypropylene pelvic mesh.

5 Q. Have you performed any testing on any
6 polypropylene surgical mesh for any application?

7 MR. PERDUE: Well, so in -- do you want to
8 know about Boston Scientific or just
9 polypropylene in general?

10 MS. STEELE: Polypropylene in general.

11 MR. PERDUE: So I need to invoke a privilege
12 that's not his because it's my understanding that
13 he has been engaged as a consultant in looking at
14 some other meshes, but I can put on the record,
15 Andrea, that he hasn't been designated and he
16 hasn't rendered a report, but it is -- it is
17 litigation-based testing. It's work product.
18 The attorney that retained him to look at it
19 obviously has a privilege on that. I have no
20 idea where it is, but I asked him have you been
21 disclosed, have you written a report, and he has
22 not.

23 So I need to invoke that lawyer's privilege,
24 but if it goes further, I will supplement as
25 necessary under the rules. I will represent to

Jimmy W. Mays, Ph.D.

1 that on the record. Okay?

2 BY MS. STEELE:

3 Q. So you have been engaged in litigant --
4 further litigation consulting and you're palming
5 testing, but at this time that testing has not been
6 disclosed or put into an expert report; is that
7 right?

8 A. That's correct, yes.

9 Q. Have you performed any nonlitigation testing
10 of any polypropylene mesh since your last Boston
11 Scientific deposition?

12 A. No.

13 MS. STEELE: And I'll go ahead and mark the
14 invoice as 12.

15 Q. When you were preparing for your deposition,
16 did you review any Boston Scientific documents?

17 A. No.

18 Q. Was your review of articles and literature?

19 A. Yes.

20 Q. In particular, the ones contained and
21 summarized in your report?

22 A. Yes.

23 Q. Did you review any additional articles
24 regarding the topics within your report that weren't
25 include -- cited within your report?

Jimmy W. Mays, Ph.D.

1 A. You know, I'm -- as a polymer chemist, I'm
2 continually reviewing the literature and I see
3 papers on polypropylene, I see papers on different
4 things, but I would say, really, that there is
5 nothing that falls specifically in the category of
6 this litigation that comes to mind.

7 Q. So, basically, there is no new literature
8 that you've seen on, you know, testing of explanted
9 transvaginal mesh that isn't in your report but you
10 reviewed it since you wrote your report?

11 A. That's correct. I've -- yeah, I've included
12 everything in my report that I was aware of at that
13 time, and I'm not aware of anything that's really
14 substantial that's been published since then,
15 although I will continue to monitor the literature.

16 (Mays Exhibit 13 was marked for
17 identification.)

18 BY MS. STEELE:

19 Q. And then I want to mark as Exhibit 13 -- and
20 can you describe what Exhibit 13 is?

21 A. Yes. I was invited to give a plenary
22 lecture at a GPC conference, it was called GPC2017,
23 in June or July of last year, it was July 19th of
24 last year, and I gave a presentation on the use of
25 high temperature GPC to characterize in vivo

Jimmy W. Mays, Ph.D.

1 oxidative degradation of polypropylene.

2 MS. STEELE: And I'm going to ahead and mark
3 that Exhibit 13 and we'll probably come back to
4 that once I have time to review.

5 BY MS. STEELE:

6 Q. Do you have any further documents in your
7 possession that are responsive to Exhibit A that
8 aren't contained within the report, including the
9 reliance list, the CV, your invoice, and then the
10 PowerPoint that haven't previously been produced to
11 Boston Scientific?

12 A. No, I think you have everything here, yeah.

13 (Mays Exhibit 2 was marked for
14 identification.)

15 BY MS. STEELE:

16 Q. I hand you what's been marked as Exhibit 2
17 and Exhibit 2 is -- do you recognize this as the
18 initial report that you gave in the Boston
19 Scientific litigation coauthored with Dr. Samuel
20 Gido?

21 A. Yes, I did.

22 Q. And this was originally written and served
23 in 2013?

24 A. I believe that's correct. Let me look at
25 the signature date. Yes, it was signed on

Jimmy W. Mays, Ph.D.

1 December 5th of 2013.

2 (Mays Exhibit 3 was marked for
3 identification.)

4 BY MS. STEELE:

5 Q. And then Exhibit 3, and do you recognize
6 Exhibit 3 as the solo-authored expert report that
7 was previously served in Boston Scientific's MDL in
8 2014?

9 A. Give me just a moment. Yes, I believe this
10 to be that report.

11 Q. And none of the opinions contained within
12 this report have changed or become invalid since you
13 wrote it, they've just been supplemented by
14 additional literature?

15 A. That's correct, yes.

16 Q. And both of those reports contain testing
17 that you or Dr. Gido had conducted for purposes of
18 this litigation; is that correct?

19 A. Yes. Both Dr. Gido and I had conducted
20 experimentation that went into this first report.
21 Now, the second report certainly contains
22 experimental data from my laboratory.

23 Q. So just -- your second report only contains
24 testing that you conducted and at that time Dr. Gido
25 was no longer involved in the litigation, correct?

Jimmy W. Mays, Ph.D.

1 A. I only see my data in this second report and
2 I really am not sure of the answer to your second
3 question about whether Dr. Gido was still involved
4 in some way or not.

5 Q. Okay. That's fine, yeah.

6 A. But he was not involved in this.

7 Q. In your authoring of the report?

8 A. Yes.

9 (Mays Exhibit 4 was marked for
10 identification.)

11 BY MS. STEELE:

12 Q. I hand you what's Exhibit 4. And is
13 Exhibit 4 the report that we received in June of
14 2018?

15 A. Yes, this -- this is it.

16 Q. And this contains your most current opinions
17 regarding polypropylene mesh and oxidative
18 degradation?

19 A. That's correct. It's mainly updated to
20 include some references that have more recently
21 appeared.

22 Q. And the extra report that's been marked as
23 Exhibit 4 does not contain the data from any of the
24 testing that you had previously conducted in the
25 Boston Scientific litigation, correct?

Jimmy W. Mays, Ph.D.

1 A. Actually, the data were not included in this
2 report because we had published the data in a
3 peer-reviewed paper, so I include reference to that
4 peer-reviewed paper and the supplementary
5 information that's available with it and I proceed
6 to discuss the key findings of that paper in this
7 report, but it seemed unnecessary now that the data
8 is out there in the peer-reviewed literature to
9 include it directly in the report.

10 Q. Okay. And keep that one close.

11 MS. STEELE: Do you need copies of anything,
12 Jim?

13 MR. PERDUE: I'm listening.

14 MS. STEELE: You're listening. I'm sure you
15 have plenty of copies of all of it.

16 (Mays Exhibit 5 was marked for
17 identification.)

18 BY MS. STEELE:

19 Q. I'm going to hand you what I've marked as
20 Exhibit 5, and these are the exhibits to the expert
21 report from June of 2018, and I'll represent to you
22 this is what was attached to your report. And there
23 is three exhibits, Exhibit A, B and C, and the first
24 exhibit, A, is your curriculum vitae. Is that
25 correct?

Jimmy W. Mays, Ph.D.

1 A. That's correct.

2 Q. And then if you turn, and it's quite a few
3 pages back due to your extensive career --

4 A. I'm getting old.

5 Q. Exhibit B.

6 A. Yes, I see it.

7 Q. And this is a list of documents reviewed by
8 you in the litigation; is that correct?

9 A. That is correct.

10 Q. And did you actively update this -- the
11 Exhibit B when you were preparing your report or
12 coordinate with counsel to update?

13 A. Yeah. I was asked by counsel to provide any
14 new references, any new information upon which I was
15 relying, and I did so.

16 Q. And did you ask for any additional documents
17 from counsel when you were preparing the report that
18 was marked as Exhibit 4, your most up-to-date
19 report?

20 A. No.

21 Q. Have you conducted any additional Internet
22 research regarding Boston Scientific or any of the
23 issues in the litigation?

24 MR. PERDUE: Objection to form. That may be
25 overbroad.

Jimmy W. Mays, Ph.D.

1 A. I really have not. Certainly, you know,
2 after I testified in some trials, I knew that there
3 was information out there and I was curious to see
4 what might be on the Internet about my testimony in
5 those trials, so I looked at that, but that's been
6 some years ago now, but I don't routinely follow,
7 you know, Boston Scientific stock or details like --

8 Q. No Google alerts?

9 A. No, no Google alerts.

10 Q. And then Exhibit C is the -- your
11 testimonial history and your compensation structure;
12 is that right?

13 A. Yes.

14 Q. And are you still being compensated at the
15 rate of \$550 per hour for deposition or courtroom
16 testimony?

17 A. Yes, I am.

18 Q. And are you still being compensated at the
19 rate of \$350 per hour for other work?

20 A. Yes.

21 Q. Do you have an estimate of the total
22 compensation you've received in the Boston
23 Scientific mesh litigation?

24 A. I don't. It's gone on for several years
25 now, obviously, around four to five years, and I've

Jimmy W. Mays, Ph.D.

1 done a lot of work in the case, so it's substantial.
2 I would say it's hundreds of thousands of dollars,
3 perhaps.

4 Q. Would you estimate it above or below
5 \$500,000?

6 A. I would estimate it as below \$500,000 but
7 probably above \$100,000, just a ballpark.

8 Q. And you've also offered expert testimony
9 against other manufacturers of mesh medical devices?

10 A. I have been deposed in matters involved
11 Ethicon and AMS, as well as, obviously, Boston
12 Scientific.

13 Q. Have you ever offered any expert report or
14 deposition testimony against Bard, CR Bard?

15 A. I have not.

16 Q. And for Ethicon and AMS, as far as your
17 total compensation, is it in the same ballpark for
18 each manufacturer as you gave me for Boston
19 Scientific, or would it be --

20 A. Boston Scientific is definitely the most
21 because I've been involved for the longest. I
22 testified in three trials there. This is my fifth
23 deposition in that case.

24 With Ethicon, considerably less; and then
25 with AMS, even less than that.

Jimmy W. Mays, Ph.D.

1 Q. For Ethicon, would you estimate under
2 \$100,000, or above?

3 A. I was deposed twice. I wrote a report. I
4 would say under \$100,000.

5 Q. And AMS, I'm assuming, is much less?

6 A. Yes, it's much less. If you want a guess
7 there, I would say maybe, I don't know, \$20,000,
8 something like that. Please don't hold me firmly to
9 those numbers.

10 Q. Yes.

11 A. I'm just trying to give you my best estimate
12 as I sit here without my billing documents in front
13 of me. I could always go back and review and give
14 you more specific information if needed.

15 Q. Okay. Thank you.

16 And then there is a list of your recent
17 trial testimony for the past four years, and that's
18 the last page of the Exhibit C, and I see Integra
19 Life Sciences Corp., vs. Hyperbranch. Was that a
20 patent case?

21 A. That was indeed a patent case.

22 Q. Did it involve polypropylene?

23 A. It did not.

24 Q. And then there are three trials and those
25 are all against Boston Scientific; is that correct?

Jimmy W. Mays, Ph.D.

1 A. That's correct.

2 Q. And is there any other trial testimony that
3 you've given in the past four years that's not on
4 this list?

5 A. No. I've certainly given additional trial
6 testimony in other cases, but I think that was all
7 in the more distant past, more than four years ago.

8 Q. Besides the pelvic mesh litigation and then
9 the other litigation that we've discussed you
10 haven't been disclosed in, are there any other
11 litigations that you are actively consulting with
12 attorneys on?

13 A. Yeah. You know, I've done a fair bit of
14 expert witness work over the past 30 years. I've
15 done some work now and then dealing with
16 polyisobutylene sealants that are used in insulating
17 glass units. I've been told that that's not
18 completely over, that it may resurface, but, yeah,
19 the main things I've been involved with recently are
20 mesh and this Integra Life Sciences vs. Hyperbranch
21 Medical Technology. That is a patent dispute over
22 surgical sealants that are used to seal wounds after
23 cranial or spinal surgeries.

24 Q. Okay. You can set that to the side.

25 And, Dr. May, since the last time you were

Jimmy W. Mays, Ph.D.

1 deposed, you have now retired; is that correct?

2 A. Yes. I retired at the end of 2017. I'm now
3 professor emeritus at the university. I don't get
4 paid for that. The big thing about it is I retain
5 library privileges, and that's so helpful to me, to
6 still be able to access the University of Tennessee
7 library.

8 Q. Do you have any active teaching or research
9 duties or obligations?

10 A. No. My last graduate student finished in
11 April. She defended her dissertation in April and
12 actually graduated in May, and I went back to the
13 university for that. She was my last student, so my
14 research operation is completely shut down there
15 now, and no teaching responsibilities either.
16 Retired life on Marco Island.

17 Q. Yes. Very good. And in preparing your
18 report that was marked as Exhibit 4, did you
19 consider any information specific to any plaintiff
20 in this Boston Scientific MDL?

21 A. Not in preparing this updated report.

22 Q. And let's go through some of the -- what I
23 noted were additions, small or larger, in your
24 report.

25 A. Okay.

Jimmy W. Mays, Ph.D.

1 Q. I wanted to first turn to page 14, and on
2 page 14 generally, you can scan it, but this page
3 deals with the specific grade of polypropylene
4 that's used in Boston Scientific's pelvic mesh
5 devices; is that right?

6 A. Yes. It discusses the Marlex HGX-030-01
7 polypropylene.

8 Q. And it contains mostly a discussion of the
9 antioxidants used in that polypropylene; is that
10 right?

11 A. Yes. There is a paragraph here that
12 describes some antioxidants, Irgonox and Irgofos,
13 that are in those materials.

14 Q. And the specific sentence that I want to
15 look at is the first full paragraph, the second
16 sentence that states: The MSDS sheets for these
17 materials state that they are not intended for use
18 in products for which prolonged contact with mucous
19 membranes, body fluids, or abraded skin or
20 implantation within the human body is specifically
21 intended, unless the finished product has been
22 tested in accordance with nationally and
23 internationally applicable safety testing
24 requirements.

25 And what opinions are you offering regarding

Jimmy W. Mays, Ph.D.

1 the safety of using Irgonox and Irgofos in a
2 polypropylene mesh for permanent implant in the
3 human body?

4 A. Simply that the manufacturer is cautioning
5 that they can have some toxicity associated with
6 them and that they shouldn't be used in permanently
7 implanted products like mesh.

8 Q. Unless the finished product has been tested
9 in accordance with nationally and internationally
10 applicable safety testing requirements?

11 A. Yes.

12 Q. Is that correct?

13 A. That's correct.

14 Q. Were the Boston Scientific pelvic mesh
15 devices, the finished products, tested in accordance
16 with nationally and internationally applicable
17 safety testing requirements?

18 A. They certainly went through some testing,
19 some biocompatibility testing, but they never, as
20 far as I've been able to ascertain, went through
21 clinical trial testing.

22 Q. Premarket?

23 A. Yes.

24 Q. Have you reviewed clinical trials
25 postmarket?

Jimmy W. Mays, Ph.D.

1 A. I have reviewed a lot of data on these
2 materials. I don't think I have actually reviewed
3 what is officially considered a clinical trial of
4 the material. Maybe I missed it.

5 Q. Could you just say -- can you -- a
6 definition of what you mean technically considered a
7 clinical trial?

8 A. To me a clinical trial is something that you
9 do before you introduce a material into the
10 marketplace.

11 Q. Okay. Are you offering an opinion about
12 whether or not the antioxidants Irgonox and Irgofos
13 are toxic if implanted permanently through a
14 finished polypropylene device?

15 A. I'm offering the opinion that they could be
16 and that the manufacturer thinks that there is some
17 cause for concern and that some testing is required.

18 Q. Are you offering an opinion as to what
19 testing is required?

20 A. No, I'm not.

21 Q. Are you offering an opinion as to whether or
22 not Boston Scientific completed the required testing
23 to demonstrate that the use of the antioxidants
24 Irgonox and Irgofos are not toxic in this
25 application?

Jimmy W. Mays, Ph.D.

1 A. They certainly did some biocompatibility
2 testing, but long-term toxic effects that extend
3 beyond that, I don't know that they did that.

4 Q. And you're not offering the opinion that
5 these are toxic antioxidants, just that they could
6 be and testing would need to be done?

7 A. They could be, yes.

8 Q. And that is based on the statement on the
9 MSDS sheets for those materials; is that right?

10 A. Yeah, and also the chemical structure of
11 these compounds and the fact that they do undergo
12 reaction when they are serving their function as
13 antioxidants, and so you really need to explore
14 thoroughly long-term both the biocompatibility of
15 the materials themselves and also the products that
16 are obtained when they do their job, when they react
17 with oxidizing agents.

18 Q. Are there any other specific sources of
19 literature or technical documents regarding the use
20 of the antioxidants Irgonox and Irgofos that you're
21 specifically relying on?

22 A. No, simply the MSDS sheets at this -- in
23 this document, yes.

24 Q. And are those MSDS sheets publicly
25 available?

Jimmy W. Mays, Ph.D.

1 A. Yes.

2 Q. So if I went on line and I found the sheets,
3 those are the same or that's how you found the
4 sheets?

5 A. There are different manufacturers that
6 produced different MSDS sheets, but the Irgonox and
7 Irgofos names identify those as Ciba products, so
8 those Ciba MSDS sheets are available online.

9 Q. And perhaps my inartful question. You did
10 not go directly to the manufacturer and ask for the
11 MSDS sheets?

12 A. No, I didn't, although, actually, they may
13 have sent them to me before because I've actually
14 used these antioxidants in the course of my
15 laboratory work, and if you order Irgonox, you will
16 receive an MSDS sheet, so --

17 Q. And in what application have you used
18 Irgonox or Irgofos?

19 A. Yeah, I particularly use these materials to
20 stabilize polydienes, like polyisoprene and
21 polybutadiene. They are also susceptible to
22 oxidative degradation.

23 Q. Are those materials used for permanent
24 implantation?

25 A. I'm not aware of an application where those

Jimmy W. Mays, Ph.D.

1 materials are used for permanent implantation, but I
2 can't completely rule it out. I simply don't know,
3 but I don't think so.

4 Q. In the materials you were developing or
5 testing, were they used for a short-term, long-term,
6 permanent implant?

7 A. They were not used as implants. These were
8 elastomeric materials that are being used as such,
9 elastomers, rubbery materials.

10 Q. Rubberly materials?

11 A. Yes.

12 Q. I wanted to turn now to page 21 of your 2008
13 expert report.

14 A. Okay.

15 Q. And specifically I want to -- so the first
16 full paragraph which is -- starts with "My research
17 group carried out a study..."

18 A. Yes.

19 Q. And this study -- I'll hand it to you, it's
20 been marked as Exhibit 6.

21 (Mays Exhibit 6 was marked for
22 identification.)

23 BY MS. STEELE:

24 Q. And is that a copy of the published study?

25 A. Yes, it is. This is the published paper.

Jimmy W. Mays, Ph.D.

1 This does not include the supplementary data, which
2 is substantial with this, but yes, this is the main
3 paper.

4 Q. And we previously discussed the details of
5 this testing and this article in detail in a prior
6 deposition; is that right?

7 A. Yes, we did.

8 Q. And the testing that's encompassed within
9 the article with lead author Imel entitled "In vivo
10 oxidative degradation of polypropylene pelvic mesh,"
11 and with you -- are you the corresponding author, is
12 that --

13 A. Yes, and -- yeah, I was a corresponding
14 author on this.

15 Q. And so the testing contained within this
16 article is testing that was completed for the
17 purposes of litigation in the Boston Scientific
18 pelvic mesh litigation, correct?

19 A. Well, this contains the characterization
20 work that was done at the University of Tennessee,
21 and also work that was done by Sam Guido in this
22 case. You know, we weren't asked by attorneys to do
23 any particular test. We were given materials that
24 were explants. I was aware of Clave's paper saying
25 polypropylene is not inert in the human body. So I,

Jimmy W. Mays, Ph.D.

1 in collaboration with Dr. Gido, outlined a series of
2 experiments that we thought would test what the
3 actual cause of degradation is.

4 Q. And that testing is -- so, basically, there
5 were two parts of the testing that you and Dr. Gido
6 tested explanted mesh materials, correct?

7 A. Yes.

8 Q. And those test results are contained within
9 your first report?

10 A. Yes.

11 Q. And then you conducted further
12 characterization testing on polypropylene pellets as
13 long as -- as well as pristine polypropylene meshes
14 for Boston Scientific, right?

15 A. That's correct.

16 Q. And that testing is outlined in the data
17 that is within your second expert report, is that --
18 which is marked as Exhibit 3; is that right?

19 A. That's correct.

20 Q. And the testing that's outlined in
21 Exhibits 2 and 3, which are your two prior expert
22 reports, are the basis for all of the data that's
23 contained within the Imel article, correct?

24 A. Yes, I believe they are the basis of all of
25 the experimental data. We did have an addendum

Jimmy W. Mays, Ph.D.

1 where we looked at the effect of bleach exposure on
2 a pristine polypropylene mesh just to make sure that
3 there is not oxidative degradation that is occurring
4 due to the bleach, and we allude to that testing in
5 here as well, so, yeah, maybe with that one
6 additional experiment.

7 Q. With the one kind of control experiment
8 using bleach on pristine mesh, there is no
9 additional testing that -- in the Imel article
10 that's not contained within Exhibits 2 and 3,
11 correct?

12 A. I think that's correct, yes.

13 Q. Now I want to turn to -- we'll discuss
14 Dr. Thames' article and the responses, but first I
15 want to talk about on page 25. On page 25 in the
16 first paragraph --

17 (Mays Exhibit 7 was marked for
18 identification.)

19 BY MS. STEELE:

20 Q. I'm going to hand you Exhibit 7, which is an
21 article with lead author Talley, and this article
22 contains two components: First, an in vitro
23 oxidative degradation test completed by Drs. Russell
24 Dunn and Scott Guelcher. Is that right?

25 A. Yes. It does contain some in vitro

Jimmy W. Mays, Ph.D.

1 oxidation testing of hydrogen peroxide plus a
2 catalyst. Who exactly conducted the experiments I
3 can't say, but, you know, I do see the five authors
4 that are here, so --

5 Q. Have you reviewed any of the test results
6 from Dr. -- any of the five authors in a form of an
7 expert report, or just through this article?

8 A. I'm not sure I understand what you're
9 asking.

10 Q. So --

11 A. You're asking have I seen their expert
12 reports?

13 Q. Have you seen their expert reports and the
14 data as laid out in those expert reports, or have
15 you only considered the published article?

16 A. I have not seen these data in any expert
17 report, only in this published one, to the best of
18 my understanding.

19 Q. Yeah. Just so I have an understanding of --

20 A. Yeah, yeah.

21 Q. -- what level of detail you have reviewed as
22 far as the data for this article.

23 And as far as -- I want to -- I know they
24 also looked at, I think especially with
25 Dr. Iakovlev's AMS mesh explanted from a patient,

Jimmy W. Mays, Ph.D.

1 they scraped material off of and then conducted some
2 different testing, but I want to focus on the in
3 vitro testing that was conducted on the Boston
4 Scientific pristine meshes.

5 A. Okay.

6 Q. And -- and they also conducted pristine in
7 -- strike that.

8 They also conducted in vitro testing, the
9 same testing on pristine Ethicon mesh, if you look
10 at the third page of the article; is that right,
11 where they have the -- they lay out in Table 1 the
12 materials?

13 A. Yes. I see two Boston Scientific materials
14 here and one Ethicon material.

15 Q. And an in vitro test is on the material
16 that's never been implanted in the human body,
17 correct?

18 A. Yeah. An in vitro test is one done
19 basically in the lab, as opposed to in vivo, which
20 is in the human, in the body.

21 Q. And if you look at the details underneath
22 that table regarding the mechanism that they used to
23 induce oxidation in this in vitro test method, they
24 placed the slings into a solution that was 20
25 percent hydrogen peroxide and 0.1 molar cobalt

Jimmy W. Mays, Ph.D.

1 chloride; is that correct?

2 A. Yes, I see that. That's correct.

3 Q. And what was the purpose of them placing the
4 polypropylene meshes into that solution?

5 A. They wanted to see the effect that the
6 strongly oxidizing solution would have on the
7 chemical structure of the polypropylene.

8 Q. And you said strong oxidizing solution?

9 A. Yes.

10 Q. And did you do any research to determine the
11 relative strengths of the oxidizing solution versus
12 the human body and the presence of oxidative species
13 in the human body?

14 MR. PERDUE: Form.

15 A. I did not try to quantify, for example, try
16 to find out if it's five times more intense than the
17 environment in the human body versus this or not, so
18 I haven't tried to quantify either.

19 Q. And as far as the in vitro test, what is
20 your main takeaway and your opinions from the
21 in vitro test that's laid out in the Talley article?

22 A. Yeah, it's exactly what I say here in my
23 report, that very recently Iakovlev -- I always have
24 trouble with that name -- and Guelcher published
25 another study where in vitro treatment of

Jimmy W. Mays, Ph.D.

1 polypropylene meshes, Ethicon and Boston Scientific,
2 for five weeks resulted in the appearance of strong
3 bands in FTIR associated with hydroxyl groups and
4 carbonyl groups. These peaks are strong
5 spectroscopic evidence for in vitro oxidation of
6 polypropylene. Pitting and meshing were observed in
7 SEM of these materials.

8 So those are the main takeaways, that they
9 did see the formation of carbonyls and hydroxyls
10 and peroxy type groups, as well as observing pitting
11 and the like in the fibers themselves.

12 Q. Does this article support your opinion that
13 poly -- Boston Scientific's polypropylene mesh
14 undergoes oxidative degradation in the human body?

15 A. This supports the fact that Boston
16 Scientific polypropylene mesh can undergo oxidative
17 degradation resulting in pitting and cracking and
18 the appearance of these hydroxyl and carbonyl bands,
19 but this is an in vitro test, not an in vivo test.

20 Q. So their tests demonstrates that Boston
21 Scientific's polypropylene mesh can undergo
22 oxidative degradation in the oxidative medium that
23 they used, correct?

24 A. Yes. That's what these in vitro experiments
25 show.

Jimmy W. Mays, Ph.D.

1 Q. The in vitro experiment -- strike that.

2 From the in vitro experiment you cannot
3 conclude that Boston Scientific's polypropylene mesh
4 will undergo oxidative degradation in the human
5 body, correct?

6 A. One would be suspicious. One certainly
7 couldn't exclude it because it's well known that the
8 foreign body response attacks implanted objects with
9 strong oxidizing agents, so you might expect to see
10 a similar oxidative attack in vivo, and that's what
11 our own testing of Boston Scientific explants shows.

12 Q. Before the Talley article and the in vitro
13 test in that article, it is conclusive evidence that
14 Boston Scientific's polypropylene mesh will undergo
15 oxidative degradation in the human body, right?

16 A. I disagree strongly, because our published
17 data was out there, and our published data was
18 before this particular paper and it shows quite
19 conclusively that oxidation is occurring.

20 Q. So if you combine your test results with the
21 test results in the Talley article, correct?

22 A. Well, Talley didn't just do the in vitro
23 testing. They also did testing of explanted
24 material. Now, it was, admittedly, an Ethicon
25 explant that was tested. I believe that's the case

Jimmy W. Mays, Ph.D.

1 here.

2 Q. Or AMS.

3 A. Yeah, let me see what it was. Was it AMS?

4 Q. I believe so.

5 A. I simply seem to recall that that explant
6 was not Boston Scientific.

7 Q. That's correct.

8 A. But they find, you know, that the material
9 is undergoing oxidative degradation, the explanted
10 material, and it's still polypropylene, whether it's
11 AMS's polypropylene or Boston Scientific's
12 polypropylene. Polypropylene is polypropylene.

13 Q. Would you expect most polymers to undergo
14 oxidative degradation in the solutions used in the
15 in vitro test?

16 A. That's a pretty broad question. I would
17 expect some to undergo oxidation. Polypropylene,
18 because of its chemical structure, is particularly
19 susceptible to oxidative degradation. If you
20 substituted polyethylene, admittedly structurally
21 quite similar to polypropylene, it would be much
22 less susceptible to in vitro oxidation under the
23 same conditions because it lacks the
24 tertiary hydrogens that are present on
25 polypropylene. Other polymers, like Teflon, to try

Jimmy W. Mays, Ph.D.

1 to give you a more complete answer, I wouldn't
2 expect to see any effect of this solution on Teflon.
3 I believe Teflon would be inert under these
4 conditions.

5 Q. Okay. Have you -- did you conduct any
6 research on polyethylene to see if in vitro testing
7 on ultra-high weight -- molecular weight
8 polyethylene had ever been subjected to the solution
9 and undergone oxidation?

10 A. I haven't actually done this type of
11 in vitro testing that they report here. I've never
12 taken that 20 percent hydrogen peroxide and catalyst
13 and put a polymer in it, but knowing what I know
14 about the reactivity of alkanes, I know that
15 polyethylene will react, it will undergo oxidation
16 for sure, and in the past I've done work with
17 polyethylene explants that were used in joint
18 replacement surgeries, this is when I was at UAB in
19 Birmingham, and we saw strong evidence that those
20 materials were oxidized in vivo.

21 But I would just expect the polyethylene to
22 be less susceptible to oxidation under the same
23 conditions. It would -- for the same time of
24 exposure to the same concentration of reagents, when
25 you take out the polypropylene, I would expect to

Jimmy W. Mays, Ph.D.

1 see more oxidative degradation than with the
2 polyethylene.

3 Q. And then I want to turn to Figure 3, which
4 is an almost full-page figure on Page 542 at the top
5 left corner.

6 A. Yes.

7 Q. And if we look down into the caption or
8 description for the figure, these pictures are meant
9 to demonstrate the different surface degradation
10 effects on the materials?

11 A. Yes. These are SEM images showing the
12 polypropylene mesh before treatment and after
13 treatment in vitro with that peroxide solution.

14 Q. And the purpose of SEM is so you can observe
15 the surface of the material to see if there has been
16 any effect on the surface, correct?

17 A. Correct.

18 Q. And you see here that there is effects on
19 the surface of the meshes after they've been put
20 into the in vitro solution, right?

21 A. Yes.

22 Q. And as described by the authors who
23 conducted the experiment, low magnification images
24 showed the knitted monofilament structure. Medium
25 magnification images revealed evidence of pits,

Jimmy W. Mays, Ph.D.

1 peeling, flakes and shallow craters on the surface.

2 Correct?

3 A. Yes.

4 Q. And in the in vitro test, they do not note
5 that there is images revealing evidence of cracking
6 in the monofilaments, correct?

7 A. I'd have to go back and review this a little
8 more carefully to be sure, but I think you're
9 correct.

10 Q. So --

11 A. Flaking, peeling and pitting is what they
12 say, such as flaking, pitting and peeling.

13 Q. And I know this isn't the best resolution
14 copy of the photographs, but looking there, you see
15 kind of an uneven surface -- surface topography due
16 to the degradation effects, especially in the last
17 row; is that correct?

18 A. I'm not sure what you -- what you mean by
19 uneven.

20 Q. So you see pits in some areas and flakes in
21 different areas and still almost smooth
22 polypropylene in other areas, right?

23 A. I'm not sure I would say smooth in any area,
24 but, yeah, some areas are certainly more damaged
25 than others, I absolutely agree with you there.

Jimmy W. Mays, Ph.D.

1 Q. So the degradative process wasn't evenly
2 around the fiber, correct?

3 A. Yeah, there were regions where it was more
4 severe than others for sure.

5 Q. And that fits in, actually, with your
6 general opinion regarding the amorphous structure of
7 polypropylene in the crystalline versus
8 noncrystalline regions; is that right?

9 A. Yeah, it's true, polypropylene is
10 semi-crystalline. The amorphous regions are much
11 more susceptible to oxidative attack because the
12 chains aren't packed as tightly together, so the
13 oxidizing agent can get in there. The crystalline
14 regions are much less susceptible to oxidative
15 degradation because they are more dense. It's
16 harder for the oxidizing agent to get in there.

17 But the actual cracking and pitting could be
18 when some amorphous regions are eroded away by the
19 oxidative agents and then, finally, just because of
20 gravity or because of physical agitation, a chunk of
21 material falls out, and that could be what's
22 resulting in some of these areas where you see pits
23 in other regions which appear to be -- I wouldn't
24 say smooth but less pitted.

25 Q. Less pitted?

Jimmy W. Mays, Ph.D.

1 A. Yes.

2 Q. And as far as the authors of this article,
3 in their description of the surface degradation they
4 do not use the word cracks, correct?

5 A. Again, I would have to go through and review
6 the whole article. Can you -- you know, when I look
7 here at the caption to Figure 3, they are saying no
8 evidence of features associated with the surface
9 degradation was observed, such as flaking, peeling,
10 or pitting under the medium magnification images.

11 But then they go on to say that medium
12 magnification images revealed evidence of pits,
13 peeling and shallow craters on the surface.

14 Q. They do not say that there is evidence of
15 cracking on the surface, correct?

16 A. Let me continue to look at it.

17 Some regions of the mesh showed evidence of
18 larger scale features such as detachment of peeling
19 flakes, but I don't specifically see the word crack
20 here.

21 Q. And if you look at these images, and if
22 you -- when you were reviewing this article, did you
23 see photographs that had the layer of transverse
24 cracking that you and Dr. Gido observed on the
25 explanted meshes?

Jimmy W. Mays, Ph.D.

1 A. I'm sorry. Could you repeat that? It was
2 kind of long.

3 Q. Yes. So -- I have a tendency to do that,
4 you may notice. I try to pack too much into one
5 question.

6 But, so, just looking at these images -- and
7 if you want to refer to your article as well, you
8 can, to look at the SEM images in your article.

9 So in your article, when you did SEM or
10 Dr. Guido performed SEM, you observed transverse
11 cracking around the polypropylene fibers, correct?

12 A. That's correct, on explanted materials that
13 had been in vivo.

14 Q. But when they did a purposefully very strong
15 oxidative in vitro test --

16 A. Yes.

17 Q. -- there is not evidence of transverse
18 cracking around the polypropylene fibers, correct?

19 A. I don't see strong evidence of it in these
20 images here, and I've got some thoughts on why that
21 could be the case.

22 Q. And turning to the AMS or the other mesh
23 that they -- the explanted mesh that's in this
24 article --

25 A. Okay.

Jimmy W. Mays, Ph.D.

1 Q. -- which I believe is on page 454.

2 A. Yes.

3 Q. And they characterize the surface -- the
4 surface of the polypropylene fibers recovered from
5 mesh explanted from a single patient with -- by XPS.

6 And XPS tests the elemental composition on
7 the surface of a material; is that right?

8 A. Yes, it -- yes, it does.

9 Q. And what they did in this test is they took
10 portions of fibers from a mesh that was explanted
11 from one patient and for half of them they scraped
12 off material and the other half they did not scrape;
13 is that right?

14 A. Yes, I believe that's correct.

15 Q. And after scraping they noted that the
16 ratios of nitrogen-to-carbon and nitrogen-to-oxygen
17 significantly decreased, right?

18 A. Yeah. Less nitrogen, much less nitrogen
19 after scraping.

20 Q. And that's because the scraping was meant to
21 remove the biologic material, right?

22 A. Exactly. These materials had never been
23 exposed to formalin to crosslink the protein, so it
24 would be easier to remove it by a physical act like
25 scraping.

Jimmy W. Mays, Ph.D.

1 Q. And just based on that, you agree that
2 formalin will crosslink protein, correct?

3 A. Oh, formalin will crosslink protein, yes, I
4 agree with that.

5 Q. Can you scrape off fatty acids absorbed to
6 the polypropylene?

7 A. Pardon?

8 Q. Can you scrape off fatty acids that have
9 been absorbed by the polypropylene mesh?

10 A. I believe you could, yes.

11 Q. You could scrape them off?

12 A. I believe you could.

13 Q. And fatty acids do not contain nitrogen,
14 correct?

15 A. Correct.

16 Q. So even if the levels of nitrogen decreased,
17 you could still have the presence of fatty acids or
18 other nonnitrogen containing biomaterial, correct?

19 A. You potentially could still have a fatty
20 acid -- repeat your question. I want to make sure I
21 really understand it.

22 Q. Okay. Even with -- so fatty acids do not
23 contain nitrogen, right?

24 A. Correct.

25 Q. So if you -- in the sample, when you do EDS,

Jimmy W. Mays, Ph.D.

1 if you do not have nitrogen, you can still have the
2 presence of fatty acids, correct?

3 A. You potentially could, but as we alluded to
4 just a few moments ago, you would expect the
5 scraping to also remove fatty acids. If you are
6 taking the protein off with scraping, I'd say you're
7 taking the fatty acids off as well.

8 Q. And they didn't perform any cleaning besides
9 scraping, correct?

10 A. Again, I'd have to go back and review their
11 protocol to make absolutely sure.

12 Q. I think it's page 448 has the protocol for
13 the XPS of the explanted polypropylene mesh.

14 A. Oh, yeah. There it is. They actually did
15 some separation using tweezers and scissors.

16 Q. Uh-huh.

17 A. So there was some separation done in that
18 way, but other than that, it was just a physical
19 scraping that was used to remove the tissue and any
20 fatty acid that might have been there as well.

21 Q. How do you ensure that you aren't
22 removing poly -- degraded polypropylene with the
23 scraping?

24 A. Well, I think you have to be careful with
25 how hard you scrape, because scraping can become

Jimmy W. Mays, Ph.D.

1 cutting if you do it too much. That's definitely
2 something that one would have to be careful about.

3 Q. Have you ever conducted testing on an
4 explanted material using scraping, tweezers and
5 scissors as your cleaning mechanism?

6 A. I have used scissors and tweezers as part of
7 just getting the mesh away from obvious bulk tissue,
8 but no, I've never used the scraping of -- but then
9 again, the materials we've had experience with, the
10 explanted Boston Scientific meshes, were materials
11 that had been exposed to formalin and, therefore,
12 the protein was crosslinked on there and you would
13 expect it to be more resistant to a scraping
14 process.

15 Q. You can set that to the side. I now want to
16 turn to -- and I'm just going to hand three exhibits
17 to you at the same time, 8, 9 and 10.

18 (Mays Exhibit 8 was marked for
19 identification.)

20 (Mays Exhibit 9 was marked for
21 identification.)

22 (Mays Exhibit 10 was marked for
23 identification.)

24 BY MS. STEELE:

25 Q. And Exhibit 8 is an article titled "The

Jimmy W. Mays, Ph.D.

1 myth: In vivo degradation of polypropylene-based
2 meshes," with lead author Shelby Thames. Is that
3 correct?

4 A. That's correct.

5 Q. The second article, Exhibit 9, is "In vivo
6 polypropylene mesh degradation is hardly a myth,"
7 with lead author Margaret Thompson. Is that

8 correct?

9 A. That's correct.

10 Q. And then Exhibit 10 is an article entitled
11 -- or a letter to the editor entitled "Reply to 'In
12 vivo polypropylene mesh degradation is hardly a
13 myth," and that also is authored by Dr. Thames,
14 correct?

15 A. Correct.

16 Q. And this is a series of articles, and then
17 comments on the article and then a letter to the
18 editor replying to the comments about the article
19 that were published in the International
20 Urogynecology Journal, correct?

21 A. That's correct.

22 Q. And the first article is testing completed
23 by Dr. Thames and others regarding explanted
24 polypropylene mesh that was manufactured by Ethicon,
25 correct?

Jimmy W. Mays, Ph.D.

1 A. Yes.

2 Q. And in your 2018 report you have a
3 discussion of this article; is that right?

4 A. Yes.

5 Q. And that's because it's recently -- it was
6 recently published in late 2016, correct?

7 A. Yes.

8 Q. Online?

9 A. Published online September 2016, correct.

10 Q. And I just want to walk through this article
11 and criticisms you have of this article, as well as
12 topics within the article that you can agree from a
13 scientific perspective are accurate, or you agree
14 with. Okay?

15 A. Okay.

16 Q. And we already discussed one, you agree that
17 formalin will crosslink protein.

18 A. Yes.

19 Q. And I know you have a kind of detailed
20 discussion of it in your report, but can you give me
21 kind of in your own words the major criticisms you
22 have of Dr. Thames's work?

23 A. Yeah. Really, he proposes this very
24 extensive cleaning protocol, a 23-step procedure,
25 and it's extremely intense. It involves use of

Jimmy W. Mays, Ph.D.

1 bleach, it involves the use of enzymes, it involves
2 extensive shaker ultrasonication process. It's
3 changes in temperature. It's really a process
4 that's so extreme that it would not only be expected
5 to take off crosslinked proteins, but it would also
6 be expected to take off oxidized polypropylene
7 layers. That's really my primary criticism of it.

8 When one tries to clean an explanted
9 material to see what has happened to it in vivo, one
10 obviously wants to remove fixated flesh to get at
11 the actual surface of the material, but one does not
12 want to strip any material at the surface that has
13 undergone changes in vivo, like oxidative
14 degradation. That's not the idea of the cleaning
15 protocol.

16 You want your cleaning protocol to be
17 selective. So you can't get too severe. And in
18 fact, Dr. Thames intentionally oxidized
19 polypropylene, exposure to UV light in the presence
20 of oxygen. That will oxidize polypropylene. And
21 then when he cleaned the material, he omitted all of
22 these ultrasonication steps. He did not use his own
23 protocol. And he said -- and I say this in my
24 report, that it would -- well, let me see exactly
25 what he said.

Jimmy W. Mays, Ph.D.

1 Yeah. Dr. Thames admitted that the first
2 six steps of his cleaning procedure, which involves
3 bleach treatment, removes the majority of the
4 proteins, and he says that the ultrasonic steps
5 of Figure 1 were omitted to prevent undue physical
6 damage and complete disintegration of the
7 polypropylene fiber.

8 I mean, Thames is admitting that the
9 ultrasonication step is extremely severe and not
10 even necessary, yet, you know, he claims with the
11 title of this paper that in vivo degradation of
12 polypropylene-based mesh is a myth.

13 Q. So the main step in the cleaning protocol
14 that you have concerns about is the ultrasonication?

15 A. That's the biggest part of it, yes, and it's
16 not just one ultrasonication, but he's doing it
17 several times.

18 Q. And I want to look -- I think we're both on
19 it. It's Figure 2 in Dr. Thames's article, and this
20 lays out the cleaning protocol that Dr. Thames used
21 on the explants as well as the exemplar control,
22 correct?

23 A. Yes.

24 Q. And what Dr. Thames did in his study was
25 perform certain cleaning steps and then he would

Jimmy W. Mays, Ph.D.

1 conduct FTIR testing on the material to characterize
2 the material, correct?

3 A. Yes.

4 Q. And he did that six times, correct?

5 A. He did what six times?

6 Q. He characterized the materials six times
7 during his cleaning process, correct?

8 A. Yes. Yes. Yes.

9 Q. And do you have an opinion as to which --
10 where in this process you start to see oxidized
11 polypropylene being removed?

12 A. I would agree basically with what Thames
13 said in his -- in his two reports that I reference
14 in my report, that the first six steps would do a --
15 quite a good job of getting crosslinked protein off
16 the material.

17 Q. So after Cleaning Sequence 1; is that right?

18 A. Well, he --

19 Q. Or before -- so before cleaning, they rinse
20 the materials and then they performed four
21 additional steps that they called Cleaning Sequence
22 Number 1, right?

23 A. Yes. I think I follow you, but he actually,
24 in this Figure 2, he calls each step out explicitly,
25 so there is 23 steps.

Jimmy W. Mays, Ph.D.

1 Q. Yeah. So you can see the different boxes --

2 A. Yes.

3 Q. -- are the first step, second step, and then
4 he has seven sequences because he conducted material
5 characterizations at certain points in the process,
6 right?

7 A. Yes, I agree.

8 Q. So when we're talking about Dr. Thames and
9 you agree that the first six steps are adequate to
10 remove the crosslinked proteins, it's the first two
11 rows which are the before cleaning rinses and then
12 Cleaning Sequence Number 1, right?

13 A. Yeah. It's the first six steps there. I
14 really don't think much happens with the first two
15 steps that he does before his characterization.
16 Rinsing with distilled water, soaking in distilled
17 water, desiccation and drying, that's not going to
18 remove a crosslinked protein.

19 But then when you get into the third step
20 and to the fourth step, where he's actually using
21 the bleach, bleach in a shaker, that is capable of
22 removing the crosslinked protein, and that's --
23 that's the sort of treatment that you typically see
24 folks working with polypropylene explants using.
25 It's usually a bleach treatment of that sort.

Jimmy W. Mays, Ph.D.

1 Q. And it's usually a bleach treatment in a
2 soaking fashion?

3 A. Yes.

4 Q. And we have seen a report of other people
5 using the bleach treatment with a shaker.

6 A. You certainly could, you certainly could.
7 There is nothing wrong with that. Ultrasonication,
8 I think, is when you start getting extreme.

9 Q. That's when you -- that's what I wanted to
10 kind of walk through. So we talked to you about the
11 first two steps?

12 A. Yes.

13 Q. And then the third step is soaking it in a
14 distilled water bath at 70 to 80 degrees Celsius?

15 A. Yes.

16 Q. Up to one day?

17 A. Yes.

18 Q. And will that step remove oxidized
19 polypropylene?

20 A. No, I don't believe that will.

21 Q. Will the fourth step, which is using bleach
22 in a shaker and the explants were in there from
23 anywhere from five minutes to six and a half hours,
24 depending on the amount of bulk tissue, will that
25 step remove oxidized polypropylene?

Jimmy W. Mays, Ph.D.

1 A. Now, are you referring to the eighth step
2 here in Cleaning Sequence 2?

3 Q. No, the fourth step in Cleaning Sequence
4 Number 1. It's the use of bleach and a shaker for
5 various times depending on the amount of bulk
6 tissue.

7 A. Yeah. That will remove a crosslinked
8 protein because the bleach hydrolyzes the peptide
9 bonds, and so it breaks down the bonds that are
10 creating this crosslinked protein network, and once
11 you break an adequate number of those bonds down,
12 then the material can simply be washed away.

13 Q. Will that fourth step, bleach in the shaker
14 for various amount of time, remove oxidized
15 polypropylene?

16 A. I don't believe it will. The bleach is
17 quite specific to cleaving the protein bonds.

18 Q. And the next two steps are a distilled water
19 rinse and a desiccation or drying. And will those
20 steps remove oxidized polypropylene?

21 A. No.

22 Q. And then at that time Dr. Thames performed
23 materials characterization, correct?

24 A. Yes, that's what it says.

25 Q. And then if you go to Cleaning Sequence

Jimmy W. Mays, Ph.D.

1 Number 2, is there any -- so at the beginning of
2 each cleaning sequence we see that they soaked the
3 explant materials in a distilled water bath at 70 to
4 80 degrees Celsius.

5 A. Yes.

6 Q. At any point in the cleaning process will
7 that remove oxidized polypropylene?

8 A. That might if you've already exposed the
9 material to ultrasonication. The ultrasonication
10 which is coming in is really the key, because --
11 maybe I can back up a little and give you a good
12 explanation.

13 When we talked about polypropylene earlier
14 we said it's a semi-crystalline material. So it's
15 roughly equal amounts by volume what I'll call
16 bricks, the crystalline regions, and mortar, the
17 amorphous regions, and really, those crystallites
18 are being held together just like a brick wall, by
19 that mortar that's there, the amorphous
20 polypropylene, and what happens is when you have
21 oxidation occurring with the polypropylene, it's
22 specific to the amorphous regions, and so you're
23 basically tearing down your mortar.

24 And then you come in with the
25 ultrasonication and the physical forces of the

Jimmy W. Mays, Ph.D.

1 ultrasonication, I called it like a molecular
2 earthquake in my report, it will literally shake the
3 material apart. It will just crumble.

4 So ultrasonication after oxidation of the
5 polypropylene is very effective. That's why
6 Dr. Thames didn't do it to his intentionally
7 oxidized polypropylene, because he knew it would
8 take the oxidized layer off and he wanted to
9 characterize oxidized polypropylene.

10 Q. Is it possible that Dr. Thames did not
11 perform ultrasonication on the intentionally
12 oxidized polypropylene because of the level of bulk
13 degradation to the material versus the surface level
14 degradation we see in explanted materials?

15 A. I don't buy that. I don't -- simply don't
16 believe that's true.

17 Q. So just looking at the protocol, where
18 things go wrong, in your opinion, is with the eighth
19 step, which is a bleach soak step using a shaker and
20 an ultrasonicator or ultrasonicator?

21 A. Yes, and then he proceeds to rinse the
22 material with distilled water and put it in an
23 ultrasonic bath again, and, you know, it goes on and
24 on with a lot of ultrasonic treatments.

25 Q. And if we go to the 16th step, which is

Jimmy W. Mays, Ph.D.

1 using a proteinase K water bath solution, soak, with
2 no ultrasonication?

3 A. Yes.

4 Q. Putting aside that they've already used
5 ultrasonication, would a proteinase K solution alone
6 remove oxidized polypropylene?

7 A. No, I don't believe it would.

8 Q. It's used to dissolve the enzymes, correct?

9 A. Yes. You can break down the
10 polypropylene -- I'm sorry. You can break down the
11 protein either by using the bleach, which hydrolyzes
12 the amide bonds in the protein, or you can use an
13 enzyme, which is also selective and will cleave
14 those protein bonds.

15 Q. And what is the basis for your opinion that
16 ultrasonication would remove a layer of oxidized
17 polypropylene?

18 A. What I just described to you, the fact that
19 oxidation breaks down the amorphous region, weakens
20 the amorphous region in the material. And so if you
21 then come in and apply ultrasound, the mechanical
22 forces from the ultrasound will cause it to crumble.

23 Q. In a uniform fashion?

24 A. If you do it enough, certainly, and I think
25 Dr. Thames is doing it plenty with these 23 steps.

Jimmy W. Mays, Ph.D.

1 I won't say that there is not some point where you
2 could apply very gentle ultrasonication and perhaps
3 only remove a portion of it. I haven't done any
4 experiments.

5 Q. Can you cite any articles that discuss
6 ultrasonication removing a surface layer from an
7 explanted material?

8 A. Other than Dr. Thames's articles?

9 Q. Correct.

10 A. Ultrasonication is sometimes used to clean
11 materials, but I think you have to be prudent about
12 applying it and be thoughtful about how you're
13 applying it, when you're applying it and what it
14 might do. In the case of an oxidized polypropylene,
15 I think it's just, you know, not a suitable method,
16 and Dr. Thames admits it with oxidized
17 polypropylene.

18 Q. Besides Dr. -- you understand Dr. Thames is
19 not an expert for Boston Scientific?

20 A. I didn't know that for sure. I know he's
21 been an expert for Ethicon, but I'm not sure about
22 his involvement with other polypropylene
23 manufacturers.

24 Q. Have you ever seen an expert report from
25 Dr. Thames regarding Boston Scientific mesh?

Jimmy W. Mays, Ph.D.

1 A. No, I don't believe I have.

2 Q. Have you ever reviewed Dr. Spiegelberg's
3 testing on Boston Scientific explanted meshes?

4 A. I have seen a couple of reports at least
5 from Dr. Spiegelberg in the past. I haven't seen
6 one in a while, but I do recall a couple of reports.

7 Q. And besides Dr. Thames' expert reports in
8 the Ethicon litigation, are there any specific
9 sources for your opinion that ultrasonication will
10 remove oxidized polypropylene from the explants?

11 A. My extensive experience in polymer science
12 and my understanding of the molecular structure of
13 these materials and their susceptibilities. I
14 really base it on my experience. I haven't tried to
15 do an extensive literature search to back it up.

16 Q. Have you done an extensive search of ASTM
17 cleaning standards to see if ultrasonication is used
18 to clean explanted materials before surface
19 characterization?

20 A. I have looked at some standards. I looked
21 at the ASTM. I looked at ISO. I was specifically
22 looking for a protocol for cleaning polypropylene
23 explants, and I was not able to find one. The
24 closest thing I found was a procedure, I believe it
25 was ISO, that's used to clean explanted

Jimmy W. Mays, Ph.D.

1 polyethylene, and they used the bleach treatment,
2 soaking in bleach.

3 So since polypropylene and polyethylene are
4 structurally similar, and since there is an
5 extensive history of folks studying explants using
6 bleach to remove the tissue, that's what we chose to
7 do.

8 Q. Okay. So your opinion that this
9 ultrasonication will remove oxidized polypropylene
10 is based on your own experience over the past 30
11 plus years in polymer science; is that right?

12 A. It's based on that. It's also based on
13 Dr. Thames's refusing to use it, refusing to apply
14 it to his intentionally oxidized polypropylene, and
15 his admission that it would do physical damage to
16 the material. He called it virtually disintegrate,
17 which I think is an overstatement, but I do believe
18 it would remove the oxidized layer, and so does
19 Dr. Thames.

20 Q. And that's with the very first
21 ultrasonication step?

22 A. Yes. I believe that with the first
23 ultrasonication step he's using a
24 shaker/ultrasonicator for one and a half to two
25 hours, he's rinsing it with distilled water, and

Jimmy W. Mays, Ph.D.

1 then he's using an ultrasonic bath for an hour
2 again, you know, something of the order of, you
3 know, two and a half to three hours of
4 ultrasonication after a bleach treatment, yeah, I
5 think that's going to start to break down the
6 oxidized polypropylene.

7 As I said earlier, whether that would take
8 absolutely all of it -- all of it off at that point,
9 I don't know. I'd have to do the experiments, but
10 certainly Dr. Thames, in his additional steps, goes
11 on to ultrasonicate again and again and again.

12 In fact, in his 21st step he's using four to
13 20 hours shaker/ultrasonicator, followed by yet
14 another one hour in an ultrasonic bath. So I think
15 after you go through the 23 steps, and Dr. Thames
16 agrees with me, you've got all the oxidized
17 polypropylene off, as well as the protein.

18 Q. What if he just used a shaker and did not
19 use the ultrasonicator?

20 A. I believe a shaker would be suitable.

21 Q. A shaker would be suitable and would not
22 remove the oxidized polypropylene layers?

23 A. Yeah. A nice gentle lab shaker I believe
24 would be perfectly suitable to use.

25 Q. And --

Jimmy W. Mays, Ph.D.

1 A. And by the way, Dr. Thames agrees. I mean,
2 he says the first six steps get the protein off, get
3 the tissue off, and he's using a shaker.

4 Q. And I wanted to look at the SE -- I'm not
5 sure if they actually are SEM. I think they are
6 just microscopic images on page -- it's Figure 4.
7 Light -- the light microscopy images, is that
8 correct, at a magnification of X200?

9 A. That's what it says here, yes.

10 Q. And this shows the -- one patient's explant
11 and it's Patient 33, and if you look at the chart of
12 the patient information, this is a mesh that was
13 implanted for 4.2 years and was in a formalin
14 fixative; is that correct?

15 A. Let me go back and look. Patient 33,
16 Patient 33 was Gynemesh implanted for 4.2 years and
17 then stored for 3.7 years.

18 I'm sorry. So I reviewed that. Now your
19 question was?

20 Q. Just that this is a patient whose mesh was
21 implanted for 4.2 years before being explanted,
22 right?

23 A. That's what it says, yes.

24 Q. And these are images after each of the
25 cleaning sequences, not individual steps but the

Jimmy W. Mays, Ph.D.

1 sequences laid out in Figure 2?

2 A. Yeah. A is before cleaning, and then B
3 through F are after the various cleaning steps.

4 Q. And at the end it looks like pristine
5 polypropylene mesh, is that right, in Picture F in
6 Figure 4?

7 A. I believe it does, yeah.

8 Q. And to the extent this patient's mesh was
9 implanted for 4.2 years, it did not undergo any bulk
10 degradation, correct?

11 A. I'm sorry. Could you repeat that?

12 Q. It didn't undergo any bulk degradation?

13 A. It's hard to say that just looking at it
14 with a light microscope at 200X, and it's especially
15 hard to say after the entire cleaning protocol is
16 applied. I think, you know, to really see
17 conclusively the damage that's occurred to the
18 material, I think you need to -- higher power,
19 higher magnification than 200X.

20 Q. Look at the same patient's explant. You can
21 see Figure 8. The picture on the right side is
22 Patient 33 once again, and this is in the image
23 magnification at 200 on SEM.

24 A. Yes, I see that.

25 Q. And there we can see the transverse cracking

Jimmy W. Mays, Ph.D.

1 on the surface layer?

2 A. Yes.

3 Q. And that is what you observed in your
4 explant testing that you published, correct?

5 A. Yeah. We observed transverse cracking on
6 polypropylene fibers, yes, explants.

7 Q. And that is not what was observed by Talley,
8 et al., in their study where they purposefully
9 oxidized polypropylene mesh, correct?

10 MR. PERDUE: Form.

11 A. Talley on the in vitro oxidized
12 polypropylene did not show this. They showed
13 pitting and flaking and the like. There are a
14 couple of reasons why the in vitro result might be
15 different. First of all, who is to say that the in
16 vitro conditions are as strongly oxidizing as the
17 conditions in vivo.

18 Secondly, and this was relevant in a case I
19 just testified in in Delaware, things in vivo are
20 different from things in vitro for various reasons.
21 In vivo is in a living, moving human being, and so
22 the combination of the chemical changes that might
23 be imparted by an oxidation process are then
24 aggravated by the person physically moving around.
25 So the movement can introduce physical forces that

Jimmy W. Mays, Ph.D.

1 cause cracking, for example, whereas when something
2 is merely floating around in a test tube, it's got
3 the chemicals acting on it but it does not have the
4 mechanical forces.

5 So it's not surprising at all that you might
6 not see this transverse cracking in the in vitro
7 experiments of the paper that we looked at earlier
8 this morning.

9 Q. You don't see the level of pitting, craters,
10 on these explant images or the explant images in
11 your study that were observed in the in vitro tests,
12 right?

13 MR. PERDUE: Form.

14 A. Could you -- could you repeat that?

15 Q. In the Talley article they observed pits and
16 crating, craters?

17 A. With their in vitro --

18 Q. In their in vitro test?

19 A. Yes.

20 Q. And in the Thames articles, as well as in
21 your explant testing, there is no pits or craters
22 observed, right?

23 A. In the Thames paper you clearly, on some of
24 these things, can see transverse cracks.

25 Q. But you can't see the types of pits and

Jimmy W. Mays, Ph.D.

1 craters we saw with the in vitro test, correct?

2 A. No, I disagree. I think you do see pits and
3 flaking.

4 Q. And it's your opinion that this cracking is
5 happening in the human body before the mesh is
6 explanted, right?

7 A. I believe that the mechanical forces that
8 the human body exerts on the mesh, in combination
9 with the oxidative effect that takes place, the
10 foreign body response, I think that that combination
11 can lead to what's commonly known as environmental
12 stress cracking.

13 Q. And if you look at Figure 11, and it's at
14 the bottom of page -- well, Figure 11, how did you
15 rule out that what is causing the cracks is the
16 formalin fixation hardening the surface layer of
17 biologic material and then that causing it to crack?

18 A. I simply don't believe that that
19 crosslinking of the poly -- of the protein that's on
20 there, that crosslinking of the polypeptide is going
21 to cause mechanical stresses on the layer underneath
22 that would cause transverse cracking. It's more
23 consistent with mechanical forces occurring in vivo
24 as opposed to something that would be an artifact of
25 the protein crosslinking.

Jimmy W. Mays, Ph.D.

1 Q. And if we look at Figure 11, these are two
2 samples that were explanted from the same patient,
3 right?

4 A. Well, let me look.

5 Yeah, these are two explants from Patient
6 56. It says the left sample was received dry, the
7 right sample was received in fixative.

8 Q. So the sample on the left, by dry, that
9 means it was never placed in formalin, correct?

10 A. I believe that's the case, but let me go
11 back and see what he's actually referring to as dry.
12 Maybe you can point me there.

13 Q. Let's see.

14 A. Yeah, I see in his materials and methods it
15 simply says 12 explants were received dry and the
16 remaining were received in fixative.

17 Q. And fixative is formalin, is what explanted
18 materials are placed in?

19 A. I would believe that to be the case, but it
20 doesn't explicitly say that here.

21 Q. But if we're looking at Figure 11, we have a
22 sample that was received dry, not in fixative,
23 whether it be formalin or a different fixative,
24 right, on the left?

25 A. That's what it --

Jimmy W. Mays, Ph.D.

1 Q. And we see a -- woops. Sorry.

2 A. Yeah. On the left, it says that one was
3 received dry.

4 Q. And the top row are light microscopy images,
5 and then we have SEM micrographs in the bottom row
6 for the two samples, right, just to orient?

7 A. Yeah. Light microscopy images are shown at
8 magnification 200X at the top, and then at the
9 bottom is SEM.

10 Q. And the example on the right was received in
11 a fixative such as formalin, correct?

12 A. The sample on the right was obtained in a
13 fixative, that's correct.

14 Q. And if you look at the SEM for the sample on
15 the left, you do not see transverse cracks on the
16 surface, correct?

17 A. And these are after Cleaning Sequence 1; is
18 that correct?

19 Q. Following, yeah, following Cleaning Sequence
20 1, so no ultrasonication has occurred.

21 A. So his cleaning sequence -- yeah, that's
22 what it says.

23 Q. So for the sample that was not placed into
24 fixative, it was kept dry, on SEM imaging after
25 Cleaning Sequence 1, where no ultrasonication has

Jimmy W. Mays, Ph.D.

1 been done, there's no transverse cracking on the
2 surface, correct?

3 A. I don't detect any in this particular image.
4 I can't see any in this particular image.

5 Q. But for the sample from the same patient
6 that was placed into a fixative after Cleaning
7 Sequence 1, you do see transverse cracking in the
8 surface layer?

9 A. Clearly, that image does show transverse
10 cracking.

11 Q. And if you look at Figure 10 at the top of
12 that page, this has -- the furthest left image is
13 from Patient 38. That was after Cleaning
14 Sequence 1, right?

15 A. Yes.

16 Q. The middle is Patient 42, which is after
17 Cleaning Sequence 5, which is the full 23-step
18 process, and then the far right picture is of the
19 TVT exemplar.

20 A. Yes.

21 Q. And if you look at the -- so Patient 38,
22 which is after Cleaning Sequence 1, which is the
23 first six steps in the cleaning process, you can
24 look at that image and you see areas where there is
25 a cracked surface coating, and then there is

Jimmy W. Mays, Ph.D.

1 pristine polypropylene fiber in another area,
2 correct?

3 A. Yeah. After Cleaning Sequence 1, it does
4 appear that there are some regions where there's no
5 transverse cracking, but other regions where there
6 are.

7 Q. So is it your opinion that the regions where
8 there is no transverse cracking, there is no
9 oxidized polypropylene or degraded polypropylene?

10 A. It's certainly possible that maybe shaking,
11 depending on how vigorously you're shaking, could
12 remove some of it. I mean, he simply says a shaker
13 for five minutes to six and a half hours. It does
14 appear that there could be a region on there where
15 the oxidized polypropylene is removed.

16 Q. Could it be that there just is no oxidized
17 polypropylene to be removed? How can you conclude
18 one way or the other?

19 A. We have our own data that we -- that we
20 generated. As I say, we used a combination of FTIR.
21 We used SEM with EDS and we saw evidence of
22 oxidation in every explanted material that we
23 received.

24 We also measured molecular weights of the
25 materials after being explanted, and the weight

Jimmy W. Mays, Ph.D.

1 average and Z-average molecular weights were
2 decreased. Clearly, the reduction in molecular
3 weight has to be from an oxidative process. I can
4 think of no other means in vivo that would reduce
5 the molecular weight of the material, and the
6 mechanism of oxidative degradation points directly
7 towards breaking of polypropylene chains.

8 Q. And without getting into the nitty-gritty of
9 molecular weight testing, but in your molecular
10 weight testing, your GPC, I think you had four
11 samples that you conducted that testing on?

12 A. Yes. We had four samples where we had
13 adequate amounts that we could test in triplicate.

14 Q. And in your results there was more of a
15 reduction in molecular weights in explants that had
16 shorter implant times than explants that had longer
17 implant times, right?

18 A. I'd have to go back and look at it to be
19 sure. We could go back and look at the table. As I
20 just sit here and as you ask me that, I can't recall
21 if there was that direct correlation or not.

22 Q. It's the GPC table, Exhibit 6, and this is
23 your article, and just looking to confirm at your
24 GPC results on Table 2 on page 141.

25 A. Yes, I'm looking at that.

Jimmy W. Mays, Ph.D.

1 Q. And we have -- the first two are controls
2 from -- one from Obtryx, one from Pinnacle, correct,
3 in the first two rows in your table?

4 A. That's correct.

5 Q. And then we see molecular weight testing
6 completed on four explant samples, right?

7 A. Yes.

8 Q. And we see that for the one that was
9 implanted for one year and seven months, it has the
10 lowest molecular weight of any of the samples that
11 you tested, right?

12 A. Yes, it does, and the others were more or
13 less comparable in terms of molecular weight, and
14 they were -- they were implanted for longer periods
15 of time.

16 Q. Longer periods of time. So when you say
17 comparable, so does 200,000 make something
18 comparable?

19 A. What do you mean does 200,000 make coming
20 comparable?

21 Q. So -- so the molecular weight difference,
22 for example, between XP-3 and XP-7 is approximately
23 200,000 -- you probably will have to help me on
24 the --

25 A. Yeah. Yeah, I would say that definitely the

Jimmy W. Mays, Ph.D.

1 648,000 Z-average molecular weight for XP-3 is lower
2 than the 874,000 Z-average molecular weight for
3 XP-7.

4 Q. And actually, the molecular weight for XP-7
5 is more similar to the controls than it is to XP-3,
6 or closer in measurement?

7 A. Yeah. It's not as degraded. Yeah, there is
8 no direct and linear correlation between the amount
9 of time the material is explanted and the reduction
10 in molecular weight that's seen.

11 Q. And turning back to Dr. Thames's article, so
12 that Mr. Perdue does not -- -- let's see. So going --

13 MR. PERDUE: I'm just glad about you being
14 in the homestretch. I'm enjoying that status.

15 Q. So we're looking at Figure 10.

16 A. Okay.

17 Q. So your opinion is that Patient 38, the
18 transverse cracked area is oxidized polypropylene
19 still?

20 A. Yes, that very much looks like oxidized
21 polypropylene of a sample that's been in vivo.

22 Q. Could it be cracked biological material?

23 A. After Cleaning Sequence 1, he's exposed it
24 to bleach and he's rinsed it, he's been shaking it.

25 As Dr. Thames himself admits, the Sequence 1 removes

Jimmy W. Mays, Ph.D.

1 protein. So the protein should be gone, so what
2 you're looking at is oxidized polypropylene.

3 Q. So if the protein is gone, you would expect
4 on EDS to have no nitrogen present, correct?

5 A. If all the protein is gone, you would expect
6 to see no nitrogen.

7 Q. And in your protocol, when you -- when
8 Dr. Guido cleaned Sample 11 with bleach to remove
9 biologic material, there was still trace nitrogen on
10 EDS, right?

11 A. You can still find trace, yes. The cleaning
12 procedure is not necessarily 100 percent.

13 Q. And similar to your results -- or did you --
14 have you observed physical mesh breakage in
15 explanted materials in your testing?

16 A. Actually seen regions where the mesh has
17 actually broken?

18 Q. Uh-huh.

19 A. Yes.

20 Q. And is it your opinion that that happened in
21 vivo, not after explant or during explant?

22 A. You certainly can't rule out some occurring
23 by the physical handling of the explant itself, but
24 I do believe that that sort of cracking could occur
25 in vivo because of the environmental stress cracking

Jimmy W. Mays, Ph.D.

1 issue that I mentioned earlier. The combination of
2 oxidize the surface, create some weak points by
3 eroding away amorphous material, and then put
4 mechanical forces on it, that can lead to cracking
5 and even breaking.

6 Q. In your table the longest explant you looked
7 at was XP-11, which was four years and 9 months.

8 A. I believe that's correct. Yes, that's
9 correct.

10 Q. And similarly, Patient 42 in Figure 10 in
11 Dr. Thames's article and -- was implanted for four
12 and a half years, if you look at his table of
13 information.

14 A. Patient 42 was 4.5 years, yes.

15 Q. And looking at after the Cleaning Sequence
16 5, you see what appears to be a pristine
17 polypropylene mesh fiber, correct?

18 A. You do, and it doesn't surprise me because
19 the entire 23-step procedure would take off oxidized
20 polypropylene as well as tissue.

21 Q. And you also can see the manufacturer's
22 extrusion striations in Patient 42's SEM micrograph,
23 correct?

24 A. I don't know. It's hard for me to say as I
25 sit here and look at this image. Maybe my eyes

Jimmy W. Mays, Ph.D.

1 aren't as good as yours.

2 Q. Comparing -- it looks similar to the picture
3 of the TVT exemplar, right? You can see the
4 striations in each?

5 A. You do see some what appears to be stripes
6 that are parallel to the fiber axis.

7 Q. Would those be caused by anything besides
8 the extrusion process?

9 A. Not that I'm aware of.

10 Q. And those are both at the same
11 magnification, correct, 200N6 and 208X, Patient 42
12 in the exemplar, so they are at similar
13 magnifications?

14 A. I'll take your word for it. I'm having
15 trouble reading that at my age.

16 Q. So at similar magnifications, you can see --
17 and the size of the fibers appears to be nearly
18 identical, correct?

19 A. Yeah, it does look to be similar in terms of
20 the dimensions of the fibers.

21 Q. In your opinion, how thick, what range --
22 how thick is the oxidized surface layer on the
23 polypropylene mesh in the explanted mesh?

24 A. I don't know. I don't know how thick it is.

25 Q. Is it a range of microns thick?

Jimmy W. Mays, Ph.D.

1 A. I would not expect it to be microns thick.

2 Q. Under a micron thick?

3 A. I -- I'm going to stick with my answer. I
4 simply don't know. I mean, we've never really tried
5 to examine how deep it goes.

6 Q. Did you try to do any quantification based
7 on the SEM images from Dr. Guido in your own study,
8 how thick that layer was in comparison to the mesh
9 fiber?

10 A. I did not know.

11 Q. How thick does the oxidized polypropylene
12 layer need to be to affect the mechanical
13 performance of the mesh?

14 A. It needs to be thick enough that you see
15 mechanical degradation on the surface, you start to
16 see things like pitting and flaking and cracking.
17 At that point, certainly it's enough.

18 Q. Is cracking alone enough, or do you need to
19 see pitting or craters?

20 A. I think cracking alone is a pretty serious
21 flaw and it might be enough.

22 Another thing you could check is the
23 compliance of the material, what's happened to the
24 modulus of the material.

25 Q. Did you perform any testing regarding the

Jimmy W. Mays, Ph.D.

1 modulus of the material?

2 A. We did not. We had limited material and we
3 chose testing specifically to test to see if
4 oxidative degradation was the -- was the reason the
5 meshes are changing in vivo.

6 Q. So for Patient 56, for the explant sample on
7 the left in Figure 11, we don't see any surface
8 degradation effects, so that patient's mesh has not
9 been mechanically affected, correct?

10 A. It's hard to make out to me what we've got
11 in the SEM on the left of Figure 11, because there
12 is something that looks like white flakes in there.

13 Q. Could that be biologic material?

14 A. I simply don't know what that material is.
15 I can't just sit here and identify it. I don't know
16 is my answer.

17 THE VIDEOGRAPHER: Ms. Steele, I have four
18 minutes left on this DVD.

19 MS. STEELE: Okay. Let's do a quick break.

20 THE VIDEOGRAPHER: Okay.

21 MS. STEELE: You can change it now.

22 THE VIDEOGRAPHER: We're going off the
23 record. The time is approximately 11:04 a.m.

24 (Recess from 11:04 a.m. until 11:19 a.m.)

25 THE VIDEOGRAPHER: We're back on the record.

Jimmy W. Mays, Ph.D.

1 The time is 11:19 a.m., and this begins Media
2 Unit Number 2. Thank you.

3 BY MS. STEELE:

4 Q. Dr. Mays, I want to talk about Dr. Thames's
5 FTIR analysis in his study, and look starting with
6 Figure 5 and then Figure 6.

7 A. Okay.

8 Q. And looking at Figure 5 first, just to
9 orient, this is the FTIR spectra for Patient 33's
10 explant before any cleaning had been done. Is that
11 right?

12 A. Yes. It's before cleaning, Patient 33.

13 Q. And we see that they have highlighted two
14 different regions in the FTIR?

15 A. Yes, I see that.

16 Q. And you see -- and they label it protein
17 amide N-H stretching --

18 A. Yes, I see that.

19 Q. -- on the far left green circle; is that
20 right?

21 A. Uh-huh. Yes.

22 Q. And do you agree with that characterization?

23 A. I believe that's correct. I don't keep all
24 of these FTIR frequencies in mind. I can certainly
25 agree that the one about 1650 is carbonyl stretching

Jimmy W. Mays, Ph.D.

1 in an amide bond.

2 Q. And that is where you would see carbonyl
3 bonds, which is evidence of oxidation on --

4 A. No. Carbonyl stretching in an amide is at a
5 lower frequency. This is at 1651, roughly.

6 Q. Uh-huh.

7 A. And you expect to see carbonyl stretching in
8 a -- something like an ester or carboxylic acid or a
9 ketone. You see that at a higher frequency,
10 somewhere between 1700 and 1740, roughly.

11 Q. So at which frequency do you look to see
12 evidence of oxidation?

13 A. You're looking to see a peak generally in
14 the range of about 1730, 1740. That's generally
15 where you see the maximum of the peak.

16 Q. So on this explanted material that hasn't
17 been cleaned, we see the peak at 1650. So that's
18 evidence of biologic material, not oxidation,
19 correct?

20 A. I believe that's correct, yes.

21 Q. And --

22 A. Although you can't rule out that there is
23 something in there at about 1750, that region we're
24 talking about, 1740, because there is a shoulder on
25 this big peak. So there could be an oxidized -- an

Jimmy W. Mays, Ph.D.

1 oxidation peak that's there but you simply can't see
2 it because of the intensity of the protein amide
3 carbonyl stretching.

4 Q. So because of the amount of protein on the
5 surface, it may be hiding the peak --

6 A. Exactly my point.

7 Q. -- for the oxidation?

8 A. Yes. You do see a little shoulder there if
9 you look. Right?

10 Q. Yeah. And that's -- and do you want to just
11 circle the shoulder you're talking about on the
12 actual exhibit?

13 A. Absolutely, that little shoulder right
14 there.

15 Q. Yeah. And Figure 6 we see -- so this is the
16 FTIR spectra for both -- the top is a blue fiber and
17 the bottom is a clear fiber from Patient 33?

18 A. Yes.

19 Q. And it shows the progression in the FTIR
20 spectra for both fibers after each cleaning sequence
21 with the identification of which cleaning sequence
22 by -- up in the left-hand corner?

23 A. Yes, I see that.

24 Q. The colors of the spectra?

25 A. I see that.

Jimmy W. Mays, Ph.D.

1 Q. And we see -- so the royal blue color is for
2 before cleaning. So that's the initial FTIR
3 spectra, similar to what we saw in Figure 5?

4 A. Yes.

5 Q. And then we see after each cleaning step the
6 change in the FTIR spectra?

7 A. Yes, I see that.

8 Q. And the two green areas are the two areas
9 that Dr. Thames and his colleagues identified as the
10 area where you would see evidence of protein in the
11 FTIR spectra, right?

12 A. Yes.

13 Q. And we see with each kind of progression of
14 the cleaning steps, the evidence of protein decrease
15 in the FTIR spectra, correct?

16 A. Well, you definitely see a decrease in the
17 evidence in all of the clean samples. It's hard for
18 me, as I sit here and look at this, that there is --
19 these things are offset with one another a little
20 bit.

21 Q. Uh-huh.

22 A. So it's hard for me to try to quantify it,
23 but there is a big difference in the amount of
24 protein that's present in the initial sample before
25 cleaning and all of the samples after cleaning.

Jimmy W. Mays, Ph.D.

1 Q. Okay. Let's look specifically at -- so the
2 royal blue colored line, which is the FTIR for
3 before cleaning.

4 A. Yes.

5 Q. And then the purple line, which is the FTIR
6 spectra after the first cleaning sequence, which is
7 after the first six steps, so no ultrasonication has
8 occurred.

9 A. Yes.

10 Q. And we see there that there is a drop in the
11 protein levels at both ME peaks between those two
12 steps, significant decrease, correct?

13 A. Yes, I would agree with that.

14 Q. And we also see at 1750 -- or no. Let's
15 see. 1730, around 1730 to 1740, where we're looking
16 for the peak of oxidation, after each cleaning step,
17 the FTIR spectra in that region, or
18 cleaning sequence -- the FTIR spectra in that region
19 remains relatively constant, correct?

20 A. It's hard for me to say with these things
21 kind of offset the way they are, but there is not a
22 huge change in there. It's hard for me to say that,
23 you know, there's less after the final cleaning step
24 as opposed to after the second cleaning step. It's
25 just --

Jimmy W. Mays, Ph.D.

1 Q. Yeah.

2 A. It's hard to tell from this. It's hard to
3 quantify from this.

4 Q. So from after Cleaning 1 through after
5 Cleaning 5, there is not a significant difference
6 between the peak at 1730 to 1740, correct?

7 A. I simply cannot tell. I simply cannot tell
8 by looking at this, the way these are presented.
9 I'm sorry.

10 Dr. Thames would have had to have gone in
11 and actually tried to quantify it in some way, just
12 visual inspection with all these FTIR spectra
13 overlay that's --

14 Q. And so focusing on -- let's just do the top
15 FTIR spectra, and I believe this is the one where
16 you see that slight shoulder that you circled.

17 A. Yes.

18 Q. And then we see the lines from each -- after
19 each cleaning sequence at 1730 and 1740 are
20 basically on top of one another, correct?

21 A. It's -- you know, that's what you were
22 trying to ask me before. I just simply can't say
23 because of the nature of these being overlaid with
24 one another.

25 When you get an FTIR spectrum, it depends on

Jimmy W. Mays, Ph.D.

1 how much of the sample that you have within the
2 beam, so to take a bunch of spectra that have been
3 run at different times and try to overlay them
4 without some quantitation and just to sit here and
5 try to look at it and make some quantitative or even
6 qualitative conclusion is very difficult.

7 Q. Okay. You can set Dr. Thames to the side.

8 And then the next two exhibits, which I believe are
9 9 and 10, and these are the kind of letter to the
10 editor back-and-forths that were engaged in --

11 A. Yes.

12 Q. -- following Dr. Thames' publication of his
13 article.

14 A. Yes.

15 Q. And I believe you said you agreed with
16 Dr. Thompson and coauthors' --

17 A. Well, I --

18 Q. -- criticisms of Dr. Thames's work?

19 A. Yeah. I basically agree with them from the
20 standpoint that there's -- had been a lot of prior
21 work to look at polypropylene and what happens to it
22 in vivo, and Dr. Thames just discarded a lot of work
23 by a lot of different people and claimed that only
24 he knew how to clean an explant properly, and so I
25 agree with Thompson, et al., in that regard. They

Jimmy W. Mays, Ph.D.

1 certainly make that point here.

2 There is a large body of published
3 literature, you know, describing degradation of
4 polypropylene, that's what they say in this paper,
5 and I agree with them on that point.

6 I also agree with them on the point that
7 Dr. Thames' procedure is very intense. It's
8 extreme. It's far beyond what's necessary to remove
9 protein and it's into the realm whereas Dr. Thames
10 admits it will basically strip everything off the
11 polypropylene fiber.

12 Q. And you understand that Dr. Thompson is a
13 attorney for plaintiffs in the mesh litigation?

14 A. I didn't know that.

15 Q. If you look at the financial
16 disclaimer/conflicts of interest on the last page of
17 the letter to the editor, we note that
18 Dr. Ostergard, Dr. Guelcher, Dr. Bendavid,
19 Dr. Iakovlev have all given medicolegal
20 consultations and testimony on the plaintiffs' side
21 in mesh litigation cases.

22 A. I see that's what it says here, yes.

23 Q. And then Margaret Thompson is actually a
24 obstetrician-gynecologist, but she also is an
25 attorney who represents plaintiffs in this mesh

Jimmy W. Mays, Ph.D.

1 litigation, correct?

2 A. I see where it says that, yes.

3 Q. And then kind of the reply to the response
4 to the article from Dr. Thames, for the most part,
5 just reiterates points from his article and then his
6 interpretation of the literature, but was there
7 anything in particular from this that stood out or
8 you wanted to respond to?

9 A. You know, he responded and the key thing to
10 me is he's responding at a time when he should have
11 known from his own experimental studies that his
12 extensive 23-step cleaning procedure would remove
13 oxidized polypropylene. He failed to do it, yet
14 he's still defending that procedure, that faulty
15 procedure at this point. That's my take-home
16 message from that.

17 Q. Okay. And I think just one point on the
18 second page in the right-hand side column. It -- he
19 notes that in an article by Dr. Iakovlev with
20 Dr. Guelcher and Dr. Bendavid, that on the -- the
21 flaked matter on the polypropylene fibers was only
22 up to five-thousandths of a millimeter thick even
23 more than 10 years after implantation.

24 A. I see where it says that.

25 Q. And if there is an oxidized -- if you accept

Jimmy W. Mays, Ph.D.

1 that the oxidative process is happening and the
2 surface layer is oxidized polypropylene, will a
3 surface layer of oxidized polypropylene that is up
4 to five-thousandths of a millimeter thick affect the
5 mechanical performance of the polypropylene mesh?

6 A. I simply don't know, and we touched on this
7 earlier today. You know, you would have to do some
8 testing to see when you -- you'd have to first test
9 how thick the layer is and correlate that with some
10 mechanical testing, such as compliance or modulus.
11 I think that would be how you would tell. I can't
12 just sit here and tell you. I'm sorry. I don't
13 know.

14 Q. Okay. And then turning back to your
15 PowerPoint, which is Exhibit 13 that you produced
16 today.

17 A. Yes.

18 Q. For the most part, this summarizes your
19 testing and then highlights certain articles from
20 the published literature regarding the testing of
21 explanted polypropylene mesh for oxidative
22 degradation, right?

23 A. That's absolutely correct. What I would say
24 is there is really nothing in there that's not in my
25 report.

Jimmy W. Mays, Ph.D.

1 Q. Okay. Can you just -- what was the
2 circumstances under which you gave this
3 presentation?

4 A. Yeah. I've known the folks at Tosoh
5 Bioscience for some years because we use GPC a lot
6 in my research. I'm considered to be something of
7 an expert in the area, and they have started to have
8 an annual or maybe biannual meeting on GPC and they
9 invited me to give the plenary lecture. I think
10 they had gotten word that I was retiring and they
11 said talk about anything you want to. I said, well,
12 how about high-temperature GPC and kind of a
13 biomaterials application, and they said sure. And
14 so I gave that presentation there as an invited
15 talk.

16 Q. And that was at Tosoh Biosciences?

17 A. Tosoh Bioscience sponsored it. The meeting
18 was held in Atlanta. I can't remember the hotel it
19 was at.

20 Q. Okay.

21 A. But it was a meeting in Atlanta in July of
22 last year.

23 Q. And was it a -- like what was -- was there a
24 title for the meeting? Was it a certain
25 organization?

Jimmy W. Mays, Ph.D.

1 A. Yeah. It was called GPC2017, which is what
2 you will see right --

3 Q. Oh.

4 A. Yeah, that's what they called it. So you
5 could -- you could look up on the Internet, I'm
6 sure, and still find some records of it, or --

7 Q. My invite must have gotten lost in the mail.

8 I just want to ask you about a couple of
9 statements that you have in the PowerPoint. We just
10 have the one copy, so I'm going to try to share with
11 you.

12 A. Sure.

13 Q. And so this is talking about your studies
14 that you did as part of your analysis of the 11
15 Boston Scientific explants, right?

16 A. Yes.

17 Q. And we see the first one says used FTIR to
18 check for oxidation and it was complicated by
19 biological material; is that right?

20 A. Yes. And what I mean by that statement is
21 these explants were in formalin, and so we know that
22 there is fixated tissue on there, so one has to
23 either use a technique that allows one to look
24 around that fixated biological tissue, such as SEM
25 EDS, which is what Gido did with all but one of the

Jimmy W. Mays, Ph.D.

1 materials, or you have to use a cleaning procedure
2 to get the material off if you're going to use
3 something like FTIR, which looks at a larger region
4 of the material.

5 Q. And for bullet -- the next bullet point
6 says: Used SEM/EDS to check for oxidation and
7 monitor mesh fiber degradation.

8 A. Yes.

9 Q. Complicated by biological material, correct?

10 A. Again, you can look at regions on the
11 surface of the fiber and you may be looking at a
12 region where there is biological material, or you
13 look at another area and you may be looking at an
14 area where there is not biological material, or a
15 minimal amount of it.

16 The key point of that study, the key finding
17 in that study was we could find regions on the
18 fibers which showed no nitrogen or only trace
19 amounts of nitrogen, but had substantial amounts of
20 oxygen. If there is equal amounts of nitrogen and
21 oxygen present, that's characteristics of an amide
22 bond, so that means protein, but if you're seeing
23 oxygen and you're not seeing appreciable amount of
24 nitrogen, that's an indicator of oxidation occurring
25 in the material, because polypropylene doesn't have

Jimmy W. Mays, Ph.D.

1 oxygen in it when it begins.

2 Q. And also in here you state no amide bands
3 were seen in FTIR but FTIR and SEM/EDS cannot
4 completely exclude fatty acid plasticization,
5 correct?

6 A. Yes, that's correct.

7 Q. That's what it states?

8 A. That's what it states.

9 Q. And that's because fatty acids show up in
10 the same -- the FTIR spectra are present at the same
11 location as you would see evidence of oxidation; is
12 that correct?

13 A. Well, fatty acids contain carbon and oxygen,
14 just like oxidized polypropylene contains carbon and
15 oxygen, so you might confuse those for one another,
16 and so that was really the main point of this study.
17 And I think the key thing -- at the time we did the
18 work, there were two schools of thought on why --
19 and Clave admits this -- why polypropylene was not
20 inert in the body. One, it's interacting in some
21 way with these fatty acids and it's a plasticizing
22 effect, or the hypothesis that oxidative degradation
23 is occurring.

24 So our GPC experiments show clearly the
25 reduction in molecular weight. That's not something

Jimmy W. Mays, Ph.D.

1 that fatty acid plasticization can do, but it's
2 entirely consistent with a known mechanism of
3 oxidative degradation of polypropylene.

4 Q. And as we discussed earlier, your study did
5 not correlate lengths of implant time with greater
6 reduction in molecular weight, correct?

7 A. We were not able to do that with the limited
8 number of samples that we had. We only had four
9 samples where we had enough material that we could
10 do the GPC experiment in triplicate. We insisted on
11 showing the reproducibility and reliability of the
12 data. I would love to have more materials that had
13 been explanted after varying periods of time, but we
14 simply used the four samples that we had.

15 I think we might see more of a correlation
16 if we had more samples. I would expect to see, if
17 we had more samples, I would expect to see more
18 degradation after longer periods of time, because
19 it's known that this foreign body response doesn't
20 stop, it continues to take place.

21 Q. And you aren't able, based on your
22 expertise, to correlate how much reduction in
23 molecular weight is necessary to result in a
24 clinical complication for a patient, correct?

25 A. I am not able to do that, you're correct.

Jimmy W. Mays, Ph.D.

1 Q. And a few more points and then I think we're
2 almost done.

3 For Dr. Spiegelberg's test method, do you
4 know how many steps are in Dr. Spiegelberg's test
5 method?

6 MR. PERDUE: In cleaning or testing?

7 Q. His cleaning method for his testing. I'll
8 restate the question so it's clean.

9 A. Okay.

10 MR. PERDUE: I'm sorry.

11 MS. STEELE: You're good. Yeah, we're good.

12 BY MS. STEELE:

13 Q. Do you know how many steps are in the
14 cleaning method used by Dr. Spiegelberg in his
15 testing in this litigation?

16 A. I saw some reports from Spiegelberg but I
17 haven't looked at them recently. I seem to recall
18 at one point in time that he put the material in
19 concentrated KOH and boiled it there for an extended
20 period, but -- that made an impression on me, but I
21 don't remember what else he might have done during
22 the cleaning. I'd be happy to review it and comment
23 but I just can't, as I sit here, recall.

24 Q. In the expert report you served in June of
25 2018 you did not include any criticisms of

Jimmy W. Mays, Ph.D.

1 Dr. Spiegelberg's testing and results, correct?

2 A. I did not, to the best of my knowledge,
3 include anything there. It doesn't mean I'm not
4 critical of them.

5 Q. And you -- and we looked. Your first report
6 in the Boston Scientific pelvic mesh litigation was
7 in 2013, correct?

8 A. Yes.

9 Q. So that was about five years ago?

10 A. Yes.

11 Q. And are you aware that doctors still widely
12 support the use of polypropylene midurethral slings
13 for the treatment of stress urinary incontinence?

14 MR. PERDUE: Form.

15 A. That wouldn't surprise me at all. They make
16 a lot of money putting these meshes into women.

17 Q. So your opinion is that doctors support
18 these midurethral slings because they are making a
19 lot of money putting them in?

20 A. I would certainly suspect there is a
21 correlation there.

22 Q. So any doctor who is implanting a medical
23 device is doing so because they are making a lot of
24 money doing it?

25 MR. PERDUE: Form.

Jimmy W. Mays, Ph.D.

1 A. Well, doctors are out to try to relieve pain
2 and symptoms, problems that people have, they are
3 out to treat it, but certainly the surgeons that
4 implant these materials, those surgeries aren't
5 cheap.

6 Q. Are Burch procedures cheap?

7 A. No, none of those procedures are cheap.

8 MS. STEELE: I think that's all the
9 questions I have.

10 MR. PERDUE: We'll reserve ours. Thank you
11 very much.

12 THE WITNESS: Thank you.

13 MS. STEELE: Thank you.

14 THE WITNESS: Thank you.

15 THE VIDEOGRAPHER: This concludes the
16 deposition. The time is approximately 11:44 a.m.

17 (Whereupon, the deposition concluded at
18 11:44 a.m.)

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Jimmy W. Mays, Ph.D.

1 C E R T I F I C A T E

2 I, SUSAN D. WASILEWSKI, Registered
3 Professional Reporter, Certified Realtime Reporter,
4 Certified Realtime Captioner, Certified Manager of
5 Reporting Services, Florida Professional Reporter,
6 and Certified Court Reporter (New Jersey), do hereby
7 certify that, pursuant to notice, the deposition of
8 JIMMY MAYS, Ph.D., was duly taken on Thursday,
9 August 16, 2018, at 9:08 a.m. before me.

10 The said JIMMY MAYS, Ph.D., was duly sworn
11 by me according to law to tell the truth, the whole
12 truth and nothing but the truth and thereupon did
13 testify as set forth in the above transcript of
14 testimony. The testimony was taken down
15 stenographically by me. I do further certify that
16 the above deposition is full, complete, and a true
17 record of all the testimony given by the said
18 witness, and that a review of the transcript was not
19 requested.

20 _____
21 Susan D. Wasilewski, RPR, CRR, CRC, CMRS, FPR, CCR(NJ)
22 (The foregoing certification of this transcript does not
23 apply to any reproduction of the same by any means,
24 unless under the direct control and/or supervision
25 of the certifying reporter.)

Jimmy W. Mays, Ph.D.

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